GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:303
ANSWERED ON:20.11.2002
IRREGULARITIES IN NEW DRUG APPLICATIONS
BALIRAM;S. SAIDUZZAMAN

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government are aware that the DCGI office has started collecting fee for the New Drug Applications and the import registration;

(b) if so, the details thereof;

(c) whether any investigations have been conducted for the irregularities; and

(d) if so, the action taken/being taken in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) Yes, Sir.

(b) The Drugs and Cosmetics Rules, 1945 were amended vide Gazette Notification GSR 604 (E) dated 24.8.2001 and GSR 900 (E dated 12.12.2001. Under GSR 604 (E)it has been made mandatory for the registration of the drugs imported into the country to ensure that only quality drugs are imported into the country. Fees for processing of the applications for registration have also been specified. Under GSR 900 (E) dated 12.12.2001 the provision for grant of approvals for new drugs by the DCG(I) has been streamlined and specific fees prescribed for processing of the applications. The fees are required to be deposited into the Consolidated Fund of India under the Head of Account `0201-Medical and Public Health, 04-Public Health - 104 Fees and FinesThe amount so far deposited under this head, for the above purpose is about Rs. 9 crores.

(c) & (d) Question does not arise.